STANDARD OPERATING PROCEDURES FOR QUALITY CONTROL IN THE PHARMACEUTICAL INDUSTRY

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Abstract

Objectives To develop quality control standard operating procedures (SOPs) and to highlight the importance of implementation and use of these SOPs in the pharmaceutical industry.

Method A pharmaceutical company, Aurobindo (Swift services), was regularly visited three times per week over a five-month period. The visits consisted of familiarisation visits followed by visits for induction and specific training. A set of SOPs were selected, developed and implemented.

Key findings Nine SOPs were developed and implemented. Seven SOPs were developed using a simple format and two SOPs were developed in the form of flow chart. The average time taken to carry out a procedure was recorded and included in eight SOPs.

Conclusion SOPs are tools which when followed correctly ensure the consistency of a process. This is important in the pharmaceutical industry to achieve high standards of quality. Inclusion of the time taken to carry out a procedure gives an indication to the user whether the task was carried out as expected.

Keywords Standard Operating Procedures, pharmaceutical industry, quality control.

Introduction

Standard Operating Procedures (SOP) are a set of written instructions to help individuals working in a particular setting to carry out specific procedures correctly. The implementation of SOPs in the pharmaceutical industry is important to attain an end result with the expected quality according to good practice guidelines.[1] SOPs should be written by qualified individuals who possess information, knowledge and experience in the particular field.[2] The header of each SOP must include the name of the department, the application field and a descriptive title. All pages of the SOP must be numbered. A Master SOP, which describes the process of SOP management, must be approved by and include the signatures of the company's authorised person and Quality Assurance manager. The procedure of the operation to be followed must be written stepwise.

The use of SOPs can prove to be beneficial in various ways.[3] SOPs inform employees about the health and safety precautions that must be taken into account when performing particular procedures and ensure that tasks are being carried out regularly whilst maintaining the quality and uniformity of batches. By correctly following SOPs, results obtained are more compliant to Good Manufacturing Practice (GMP) requirements.

Method

A pharmaceutical company, Aurobindo (Swift services), was regularly visited three times per week over a five-month period. Various meetings were held with the company manager, head of quality assurance, head of quality control departments and laboratory technicians to discuss the need for implementation of SOPs. The visits consisted of nine familiarisation visits followed by visits for induction and specific training. Following training and an intensive literature review, nine SOPs were chosen for development.

During SOP development, it is important to keep in mind the individual who will be following and performing the particular procedure to determine the amount of information which should be included. The SOPs were written with sufficient detail and information to be followed correctly by an individual with basic knowledge and who does not have much experience with a particular procedure. All information in the SOP was written using simple and concise language and each step in the procedure was written in the imperative form.

There are three types of SOP formats; simple, graphic and flow chart. The selected SOP format depends on the number of decisions to be taken and the number of steps and sub-steps which are needed to organise and structure each SOP.[4] Short procedures with a few decisions are written in simple steps format while long procedures that require a small number of decisions are written in hierarchical steps or graphic format. Procedures that require more decisions to be taken are written in the form of a flow chart. Simple and

Simple steps	Flow chart
Dissolution testing	Purified water testing
Friability testing	High Performance Liquid Chromatography (HPLC)
Operation of analytical balance	
Karl Fisher Titrino	
Infra red identification test	
Disintegration testing	
Identification by Thin Layer Chromatography (TLC)	

Table 1: List of SOPs developed

flow chart formats were chosen to develop the SOPs. Each SOP was tested twice by two laboratory technicians and the average time to perform each procedure was taken.[5-7] The average time taken was included in eight SOPs.

SOP implementation must be effective and best conducted in the work place. The users were trained to follow the SOPs to perform the procedure correctly. The individual responsible for training explained why and how each step in the SOP must be carried out. It was stipulated that each SOP should ideally be reviewed and updated every 6 months.

Results

Nine SOPs were developed and implemented (Table 1). Seven SOPs were written using simple format and two SOPs were written in the form of a flow chart.

The SOPs were developed to attain intended results with respect to compliance with European Pharmacopeia requirements with regards testing of a product's quality. The sections included in each SOP are listed in Table 2.

Discussion

The production of high quality medicinal products is very important for the pharmaceutical industry. The best way to achieve these goals is through SOPs. SOPs are important tools in the pharmaceutical industry and help users to perform the various activities required for the quality control and quality assurance of the product. The success of the pharmaceutical industry relies upon following the SOPs correctly. SOPs have an essential role in the pharmaceutical industry since by following SOPs the requirements of GMP and the European pharmacopeia are met and the expected quality is achieved.

Recording the average time taken to carry out the procedure in the SOP may help the user realise if the procedure was carried out correctly. If the user spends more or less time performing the procedure than is specified in the SOP, this indicates that the user may not be carrying the particular procedure appropriately.

SOP sections
1. Purpose
2. Scope
3. Application field
4. Average time taken
5. Procedure
6. Diagram of instrument
7. European acceptance criteria

Table 2: SOP sections

The main limitation for this study was that not enough time was available to develop the complete library of quality control SOPs for this company. Another limitation was that the time taken to follow the SOP for HPLC testing was difficult to determine since this varied according to the sample being tested.

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